

RECEIVED
CENTRAL FAX CENTER

PATENT

OCT 22 2007 10/613,788

In the Claims:

This version of the claims replaces all prior claims.

1. (currently amended) A method of treating a patient requiring long-term therapy following hematopoietic cell transplantation having graft-versus-host disease or following organ allograft transplantation having host-versus-graft disease, the method comprising long term topical oral administration of a topically active corticosteroid wherein treatment is directed to tissue selected from the group consisting of intestine and liver and further wherein the topically active corticosteroid is initially administered at least 29 days post transplantation.

2. (previously presented) The method of claim 1 wherein the topically active corticosteroid is administered orally at a dosage of 4 mg per day to 12 mg per day.

3. (previously presented) The method of claim 1 wherein the patient has tissue damage and the tissue is intestinal mucosa.

4. (previously presented) The method of claim 1 wherein the patient has tissue damage and the tissue is small bile ducts in the liver.

5. (previously presented) The method of claim 1 wherein the patient has tissue damage and the tissue damage is inflammation.

PATENT
10/613,788

6. (previously presented) The method of claim 1 wherein the patient has tissue damage and the tissue damage is destruction of the mucosa of the intestine.
7. (previously presented) The method of claim 1 wherein the topically active corticosteroid is administered orally from day 29 to day 56 following hematopoietic cell transplantation.
8. (previously presented) The method of claim 1 wherein the topically active corticosteroid is administered in combination with prednisone and prednisolone at 2 mg/kg.
9. (previously presented) The method of claim 1 wherein the topically active corticosteroid is formulated for oral administration in the form of a pill, capsule or microsphere.
10. (previously presented) The method of claim 7 wherein the of topically active corticosteroid is formulated such that the pill, microsphere, or capsule dissolves in the stomach, small intestine or colon.
11. (previously presented) The method of claim 1 wherein the topically active corticosteroid is formulated for oral administration in the form of an emulsion.
12. (previously presented) The method of claim 1 wherein administration of the topically active corticosteroid initiates following infusion of the hematopoietic cells.

PATENT
10/613,788

13. (previously presented) The method of claim 1 wherein administration of the topically active corticosteroids ceases after 80 days following infusion of the hematopoietic cells.

14. (previously presented) The method of claim 1 wherein the patient is the recipient of HLA-mismatched hematopoietic stem cells.

15. (previously presented) The method of claim 1 wherein the patient is the recipient of unrelated donor hematopoietic stem cells, umbilical vein hematopoietic stem cells, or peripheral blood stem cells.

16. (previously presented) The method of claim 1 wherein the topically active corticosteroid is administered in combination with other prophylactic agents.

17. (previously presented) The method of claim 1 wherein the topically active corticosteroid is beclomethasone dipropionate.

18. (previously presented) The method of claim 1 wherein the topically active corticosteroid is alclometasone dipropionate, budesonide, 22S budesonide, 22R budesonide, beclomethasone-17-monopropionate, clobetasol propionate, diflorasone diacetate, flunisolide, flurandrenolide, fluticasone propionate, halobetasol propionate, halcinonide, mometasone furoate, or triamcinalone acetonide.